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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,226	09/29/2003	Tony Romeo	14233.10USU1	1700

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/675,226	ROMEO ET AL.	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group VII in the response dated 11/21/2005 is acknowledged, however, the previous restriction (dated 9/21/2005) grouped patentably distinct methods of use. As such, a new restriction requirement is set forth below.

Claims 1-9 are use claims that are interpreted in the following restriction requirement as methods of making a medicament, and not as product claims.

Claims 10-13 are use claims that are interpreted in the following restriction requirement as methods of modulating polysaccharide adhesin synthesis, and not as product claims.

Claims 27-30 are use claims that are interpreted in the following restriction requirement as methods of improving the response of a patient, and not as product claims.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to the use of a polynucleotide having the sequence set forth in SEQ ID NO: 1 to prepare a medicament, classified in class 536, subclass 23.7.

II. Claims 4-6, drawn to the use of a polynucleotide having the sequence set forth in SEQ ID NO: 2 to prepare a medicament, classified in class 536, subclass 23.7.

III. Claims 7-9, drawn to the use of a polynucleotide having the sequence set forth in SEQ ID NO: 3 to prepare a medicament, classified in class 536, subclass 23.7.

IV. Claims 10-11, drawn to the use of an amino acid sequence comprising SEQ ID NO: 1 in modulating polysaccharide adhesin synthesis, classified in class 530, subclass 350.

V. Claims 10 and 12, drawn to the use of an amino acid sequence comprising SEQ ID NO: 2 in modulating polysaccharide adhesin synthesis, classified in class 530, subclass 350.

VI. Claims 10 and 13, drawn to the use of an amino acid sequence comprising SEQ ID NO: 3 in modulating polysaccharide adhesin synthesis, classified in class 530, subclass 350.

VII. Claims 14-15, drawn to methods of identifying inhibitors of ycdQ, classified in class 435, subclass 7.1.

VIII. Claims 14 and 16, drawn to methods of identifying inhibitors of ycdR, classified in class 435, subclass 7.1.

IX. Claims 14 and 17, drawn to methods of identifying inhibitors of ycdS, classified in class 435, subclass 7.1.

X. Claims 18-19 and 31, drawn to methods of reducing the rate of conversion of UDP-GlcNAc by reducing expression of ycdQ, classified in class 435, subclass 471.

XI. Claims 18, 20-21, and 31, drawn to methods of reducing the rate of conversion of UDP-GlcNAc by reducing expression of ycdR, classified in class 435, subclass 471.

XII. Claims 22-25, drawn to methods of inhibiting polysaccharide deacetylation and adhesin transport by reducing ycdR activity, classified in class 435, subclass 471.

XIII. Claims 26, 32, and 36, drawn to methods of reducing adhesin binding by reducing ycdS activity, classified in class 435, subclass 471.

XIV. Claims 27-28, drawn to the use of an inhibitor of a product of the ycdSRQP operon in the treatment of a mammal, classified in class 424, subclass 94.1.

XV. Claims 29-30, drawn to the use of an inhibitor of the expression of a product of the ycdSRQP operon in the treatment of a mammal, classified in class 514, subclass 44.

XVI. Claims 33-35, drawn to a method of reducing adhesin synthesis by reducing ycdQ activity, classified in class 435, subclass 471.

XVII. Claims 37-39, drawn to a polynucleotide having the sequence of SEQ ID NO: 1, classified in class 536, subclass 23.7.

XVIII. Claims 40-42, drawn to a polynucleotide having the sequence of SEQ ID NO: 2, classified in class 536, subclass 23.7.

XIX. Claims 43-45, drawn to a polynucleotide having the sequence of SEQ ID NO: 3, classified in class 536, subclass 23.7.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XVI are related as methods. The methods are distinct from one another because they have different goals as evidenced by the preamble (Use of SEQ IDs 1-3 to make medicament; Use of SEQ IDs 1-3 in modulating adhesin synthesis; methods of identifying inhibitors of ycdQ, ycdR, ycdS; methods of reducing conversion of UDP-GlcNAc; methods of inhibiting polysaccharide deacetylation and adhesin transport; use of inhibitors of ycdSRQP operon), different method steps (preparing medicament; modulating adhesin synthesis; reducing expression of ycdQ, ycdR; reducing activity of ycdR, ycdS, ycdQ), and have different final outcomes. Consequently, each method is distinct from the other.

Inventions XVI, XVIII, and XIX are related as products which share an alleged common utility of modulation of polysaccharide adhesin synthesis in biofilm-forming bacteria but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the nucleic acids can be used for vaccination to make antibodies or protect from infection.

Inventions XVII-XIX and I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polynucleotides of Inventions XVII-XIX can be used as DNA probes.

The products of Inventions XVII-XIX are separate and distinct from the methods of Inventions IV-XVI, wherein the products of Inventions XVII-XIX may neither be made by nor used in the methods of Inventions IV-XVI. In the instant case, the products of Inventions XVII-XIX are polynucleotides whereas the methods of Inventions IV-XVI use polypeptides or inhibitors.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully

examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian Gangle
3/3/2006

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER